IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

| JOSEPH HILL, et al., |) | |
|---|-------------|------------------|
| Plaintiffs, |) | NO. 3:21-cv-0440 |
| V. | j | JUDGE RICHARDSON |
| MEDICAL DEVICE BUSINESS SERVICES, INC., |))) | |
| Defendant. |) | |
| |) | |

MEMORANDUM OPINION

This case concerns the breakage of a surgical implant used in the hip replacement surgery of Plaintiff Joseph Hill and the alleged resulting injuries to Mr. Hill and his wife, Tracy Hill. Pending before the Court are "Plaintiffs' Motion in Limine to Exclude Evidence that Mr. Hill's Surgeons Were the Cause of the Product Failure" (Doc. No. 40, "Plaintiffs' MIL"), "[Defendant's] Motion to Exclude the Testimony and Opinions of Julia Greer, Ph.D." (Doc. No. 51, "Motion to Exclude Dr. Greer"), "[Defendant's] Motion to Exclude the Testimony and Opinions of W. David Merryman, Ph.D." (Doc. No. 53, "Motion to Exclude Dr. Merryman"), "[Defendant's] Motion for Summary Judgment" (Doc. No. 55, "Summary Judgment Motion"), "[Defendant's] Motion to Strike and Exclude Plaintiffs' Expert Declarations" (Doc. No. 73, "Motion on Expert Declarations"), and "[Defendant's] Motion to Strike and Exclude Declaration of Tracy Hill" (Doc. No. 74, "Motion on Tracy Hill's Declaration").

For the reasons given herein Plaintiffs' MIL is DENIED, the Motion to Exclude Dr. Greer is GRANTED, the Motion to Exclude Dr. Merryman is GRANTED, the Summary Judgment

Motion is GRANTED, the Motion on Expert Declarations is DENIED, and the Motion on Tracy Hill's Declaration is DENIED.

BACKGROUND

I. Undisputed Facts¹

On August 14, 2014, Mr. Hill underwent a total hip arthroplasty (commonly known as hip replacement surgery) on his right hip during which his surgeon, Dr. William Kurtz, implanted the subject CORAIL® femoral stem ("Implant"). A femoral stem is one of multiple modular components that fit together to form a "total hip replacement." At the time when he recommended

There are other purported facts that are not undisputed but are evidentially supported and are asserted by Plaintiffs or Defendant, as the case may be, to support their respective views that there is (according to Plaintiffs) or is not (according to Defendant) a genuine issue of material fact as to a particular claim. The Court refers to these purported facts, and the evidence supporting them, in appropriate places in its analysis below.

It is worth stating the undersigned's view of all of this. Admittedly he has derived this view on his own, without having particularly clear authority that put it all together, but he is confident in the soundness of his view. In a statement of undisputed facts, a summary judgment movement must, under Fed. R. Civ. P. 56(c)(1)(A) and this Court's Local Rule 56.01, support the assertion of each fact with a citation to the record that supports the truth of the asserted fact. But neither rule requires the movement to cite to admissible evidence. Instead, the (purported) inadmissibility of the materials cited by the movant arises if and when the non-movant "assert[s] that a fact . . . is genuinely disputed." Fed. R. Civ. P. 56(c)(1). If the non-movant makes such an assertion, the assertion must be supported, in one of two alternative particular ways: by "showing [either] that the materials cited do not establish the absence or presence of a genuine

¹ The facts set forth in this section are undisputed. Some come from the statements of undisputed facts, (Doc. Nos. 67, 68, 71), wherein they are not disputed by one party in response to the other's assertion of them. Some the Court deems undisputed, because the alleged dispute is not cognizable for other reasons as exemplified in the following footnote. Still other facts come from depositions of Plaintiffs or Plaintiffs' experts and are cited (as being accurate) by Defendant in its briefing. Other facts are mutually stated in the parties' briefing. Moreover, the Court treats certain facts as undisputed because Plaintiffs have cited only their own statements—which make a wholly conclusory denial of these facts—in their own declarations to deny those facts, and the declaration does not adequately show that the applicable Plaintiff(s) has personal knowledge to support the (wholly conclusory) statement of denial.

² This fact exemplifies the Court's point in the prior footnote. Plaintiffs' response to Defendant's Statement of Undisputed Facts purported to dispute this fact based on Plaintiffs' assertion that the material Defendant cited to support this fact was not admissible evidence. (Doc. No. 67 at 3). But Plaintiffs do not actually dispute the truth of this fact because the gist of this fact was largely admitted via Plaintiffs' agreeing with a later paragraph in the same Statement of Undisputed Facts that contained largely the same information (*id.* at 8) and is accepted by Plaintiffs' experts as an accepted fact in their analyses (analyses that Plaintiffs endorse).

and implanted the Implant into Mr. Hill's right hip, Dr. Kurtz was aware that the Implant ran a risk of what is known as "fatigue fracture."³

Following the surgery, Mr. Hill continued to experience pain in his groin and thigh and, following several months of continued pain, he sought a second opinion from a different orthopedic surgeon, Dr. Brian Perkinson. Beginning in early 2015, Dr. Perkinson conducted a massive workup and review of Mr. Hill's symptoms, ultimately diagnosing Mr. Hill with a "leg length discrepancy" and an "offset deficiency" of approximately 10 mm. On September 4, 2015,

dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(B). So it is true that to assert that a fact is genuinely disputed, it would be appropriate and effective for a non-movant to point out that the movant has cited only inadmissible evidence to support a purportedly undisputed fact; so doing can be part—but only part—of a showing that the movant "cannot produce [as opposed to merely has not yet produced] admissible evidence to support the fact." But it is not effective unless the non-movant asserts that a fact is genuinely disputed; where the non-movant does not so assert, the issue of whether the movant has cited admissible evidence to support the truth of the fact is not even reached. This makes perfect sense; the purpose of a summary judgment movant's statement of (purported) facts, together with the non-movant's response thereto, is to determine what facts are in genuine dispute—and if it can be disputed that a fact is not in genuine dispute, the purpose has been served without the need for the court or the parties to spend resources analyzing the admissibility of cited evidence to support the truth of a fact that is not genuinely disputed anyway.

As paraphrased by the Court above, the fact that Defendant here asserts is undisputed is that a femoral stem is one of multiple modular components that fit together to form a "total hip replacement." In their response to this asserted fact, Plaintiffs stated, "Disputed. Defendant relies on unauthenticated, inadmissible testimony. Under Rule 56(c)(2), Defendant objects that the link cited to support this fact is not presented in a form admissible in evidence." (Doc. No. 67 at 3). In context, it seems apparent that Plaintiffs' statement that this fact is "disputed" is not actually an assertion that this fact is in genuine dispute, but rather an assertion only that the fact (whether or not genuinely disputed) was not supported by Defendant via citation to admissible evidence—an assertion that, as discussed above, is not even reached unless Plaintiffs assert that the fact is in genuine dispute. So Plaintiffs' alleged "disput[ing]" of this fact is ineffective.

The ineffectiveness can also be characterized as Plaintiffs' failure to "show[] [either] that the materials cited do not establish the absence or presence of a genuine dispute, or that [Defendant] cannot produce admissible evidence to support the fact." That is, Plaintiff provides no discussion that suffices to show (as opposed to conclusorily assert) either (a) that the materials cited (considered without regard to their admissibility) do not establish the absence of a genuine dispute; or (b) that the Defendant cannot produce (as opposed to has not yet produced) admissible evidence to support that fact.

The upshot of this discussion is that a non-movant will never succeed in disputing a statement of fact by merely stating that the cited material is inadmissible, as occurred here. A non-movant must explain why a genuine issue of fact exists in either of the ways listed above.

³ From the various experts' testimony, the Court takes "fatigue fracture" to mean a fracture that occurs due to the cumulative effect of stresses (cyclical loading) put on the device over time.

Dr. Perkinson performed a revision surgery on Mr. Hill's right hip, during which he left the Implant in place but swapped out two of the modular components of the total hip replacement construct, allowing him to add length to the structure without replacing the Implant. While Mr. Hill seemed to show some improvement during the initial postoperative period, the groin pain returned. Ultimately, the 2015 revision surgery failed to correct Mr. Hill's pain, and Mr. Hill continued to experience hip pain through June 2020.⁴

On June 9, 2020, while walking in the park with his wife, Mr. Hill collapsed with a sudden onset of pain. Mr. Hill was taken to the hospital, where he was diagnosed with a fracture of his Implant. On June 12, 2020, Dr. Perkinson performed another revision surgery, this time removing and replacing the entire total hip replacement construct (including the fractured Implant).

II. Relevant Procedural Background

Plaintiffs assert the following claims,⁵ all grounded on injuries resulting from the Implant breaking: strict products liability for design defect; strict products liability for manufacturing defect; negligence; negligent infliction of emotional distress to Mrs. Hill; and loss of consortium for Mrs. Hill. (Doc. No. 1, "Complaint," at 14–18).

Plaintiffs and Defendant both sought out, retained, and disclosed experts. Plaintiffs' experts and Defendant's experts seem to agree that the Implant broke because of a small flaw⁶ in the Implant's metal, but they disagree as to how that flaw came to exist. Defendant's experts assert that a flaw was introduced to the product during surgery from the use of electrocautery and that

⁴ Mr. Hill sought a third opinion from another orthopedic surgeon, Dr. Michael Christie, to determine whether there was any other potential treatment that might be available to him. This fact is not material to the case.

⁵ Plaintiffs do not seek to recover any damages for any pain and suffering that pre-dated the breakage.

⁶ For purposes of the discussion herein, a "flaw" means an imperfection in the metal. It is not synonymous with the term "defect," which is defined and used herein according to its legal meaning.

neither Defendant nor the surgeons would have known about the flaw at the time of Mr. Hill's surgeries. Plaintiffs' experts are: Dr. Julia R. Greer, an expert in metallurgy; Dr. W. David Merryman, an expert in biomechanics; and Dr. Brian Dierckman, an orthopedic surgeon. Based on Plaintiff's experts' collective opinions, Plaintiffs assert that a flaw was introduced to the product during the manufacturing process. Plaintiffs' experts collectively rule out alternative causes—such as electrocautery and other actions during surgery—so as to purportedly leave a manufacturing defect as the only viable reason for the breakage.

Both Plaintiffs and Defendant have filed respective motions to limit the other side's use of expert testimony. After Defendant produced its expert reports, Plaintiffs filed Plaintiffs' MIL to exclude any expert testimony that the surgeons caused the Implant's failure. Plaintiffs argued that Defendant could not properly rely on evidence of comparative negligence on the part of the surgeons, because Defendant had not pled a comparative-negligence defense. (*See generally* Doc. No. 40). Defendant subsequently filed separate motions to exclude the expert testimony of Drs. Greer and Merryman, respectively (Doc. Nos. 51, 53, collectively "Motions to Exclude Drs. Greer and Merryman") and its Summary Judgment Motion.

In their response in opposition (Doc. No. 65) to the Motion to Exclude Dr. Greer, Plaintiffs attached a declaration of Dr. Greer (Doc. No. 65-1). They likewise attached a declaration of Dr. Merryman (Doc. No. 64-3) to their response in opposition (Doc. No. 64) to the Motion to Exclude Dr. Merryman. And in their response in opposition (Doc. No. 66) to Defendant's Summary Judgment Motion, Plaintiffs attached declarations of Dr. Dierckman (Doc. No. 66-2) and Mrs. Hill (Doc. No. 66-3). According to Defendant, these declarations contradicted admissions that the experts and Mrs. Hill previously made, and that Defendant relied on in its Motions to Exclude Drs.

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⁷ Attachments listed herein are not an exhaustive list.

Greer and Merryman and in its Summary Judgment Motion. Seeking to have the Court exclude or strike these declarations, Defendant filed its Motion on Expert Declarations and Motion on Tracy Hill's Declaration.

DISCUSSION

I. Defendant's Motions to Exclude Drs. Greer and Merryman.

The Court first turns to Defendant's Motions to Exclude Drs. Greer and Merryman. The Court does not need to start instead with Defendant's Motion on Expert Declarations, because (as explained below) Plaintiffs could not withstand summary judgment even if the Court declined to exclude the targeted declarations.

A. Legal Standard

In its current form, Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue:
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. The rules thus lists four requirements to the admissibility of expert testimony, not counting the foundational requirement that the purported expert be actually "qualified as an expert by knowledge, skill, experience, training, or education."

The party offering the expert has the burden of proving admissibility. *Boatman v. Comcast of S.*, No. 3:17-cv-536, 2020 WL 714146, at *7 (Feb. 12, 2020); *E.E.O.C. v. Kaplan Higher Educ. Corp.*, 748 F.3d 749, 752 (6th Cir. 2014) ("Rule 702 provides that '[a] witness who is qualified as

an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if[,]' among other requirements, the testimony 'is based on sufficient facts and data' and 'is the product of reliable principles and methods[.]' Fed. R. Evid. 702(b), (c).")

"When making a preliminary finding regarding an expert's qualifications . . . the court is to examine 'not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Smelser v. Norfolk S. Ry.*, 105 F.3d 299, 303 (6th Cir. 1997) (citation omitted); *accord Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020). "In exercising this gatekeeping role, a district court, after concluding that the witness is qualified to testify as an expert, must evaluate whether the witness will offer an opinion that will 'help the trier of fact to understand the evidence or to determine a fact in issue." *Gales on behalf of Ranson v. Allenbrooke Nursing & Rehab. Ctr., LLC*, 91 F.4th 433, 435–36 (6th Cir. 2024) (quoting Fed. R. Evid. 702(a)).

"In addition, *Daubert* provided a non-exclusive checklist for trial courts to consult in evaluating the reliability of expert testimony. These factors include: 'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting *United States v. Langan*, 263 F.3d 613, 621 (6th Cir.2001)). This test is "flexible" and "may be tailored to the facts of a particular case," *Id.* (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)), and "the district court has 'broad latitude' as to which factors to consider in a particular case." *E.E.O.C. v. Kaplan Higher Educ. Corp.*, 748 F.3d 749, 752 (6th Cir. 2014) (quoting *Kumho*, 526 U.S. at 142). Indeed, the Sixth Circuit has advised:

Multi-factor tests, especially non-exhaustive tests, run the risk of obscuring the core inquiry. The key handholds of Rule 702 thus bear repeating: To be admissible, any

relevant scientific or technical evidence must be the "product of reliable principles and methods" and must have been "reliably applied" in the case. That is what matters most. Otherwise, the central point of *Daubert*, to establish that Evidence Rule 702 "displaced" the common law *Frye* test, would be lost and would lead to the replacement of an old common law test with a new (harder to pronounce) common law test. *Compare Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), with *Daubert*, 509 U.S. at 585–89, 113 S. Ct. 2786. That is not progress.

United States v. Gissantaner, 990 F.3d 457, 463 (6th Cir. 2021).

On the one hand, reliability does not require the best method or data. On the other hand, it requires a factual basis that is adequate under the circumstances. "Although Rule 702 does not require an expert to consider all the facts and data available, it does require the factual basis of his opinion to be sufficient[,]" United States v. Lang, 717 F. App'x 523, 536 (6th Cir. 2017) (citing Fed. R. Evid. 702), and "an expert may not be permitted to testify to the jury when his opinion rests only on facts that 'plainly contradict' undisputed evidence[,]" id. (quoting Greenwell, 184 F.3d at 498). "Expert testimony based on 'shaky' evidence is admissible, so long as the testimony is not based on 'guesses' or 'assumptions.'" Kiser v. Terumo Med. Corp., No. 2:21-CV-69, 2023 WL 4778447, at *5 (E.D. Tenn. July 26, 2023) (quoting Jahn v. Equine Servs., PSC, 233 F.3d 382, 393 (6th Cir. 2000)). "However, a 'court is not required to admit expert testimony "that is connected to existing data only by [an assertion without proof] of the expert" and 'may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Id. (quoting Nelson v. Tenn. Gas Pipeline Co., 243 F.3d 244, 254 (6th Cir. 2001) (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997))). Similarly, reliability does not require correct, credible, or accurate conclusions. See In re Scrap Metal Antitrust Litig., 527 F.3d at 529. In other words, a district court can find Rule 702's requirement of reliability satisfied even without independently finding that the expert's conclusions necessarily are correct, credible, or accurate—a finding that would be left to the jury to make (or decline to make) if the testimony is admitted.

Changes to the language of Rule 702 in two respects (one more primary than the other) took effect December 1, 2023. Under the secondary change, which involves a rather nuanced change in language, the requirement that "the expert has reliably applied the principles and methods to the facts of the case" has become a requirement that "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Under the primary and more significant change, the four requirements to admissibility of expert testimony are now proceeded by a requirement that "the proponent demonstrates to the court that it is more likely than not that" these requirements exist; this language clarifies who bears the burden on the preliminary question of whether these requirements are satisfied—and by what standard of proof (namely, a preponderance)—a court must find them satisfied when deciding, under Rule 104(a), this preliminary question of admissibility. "First, the rule has been amended to clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule. . . . [T]he amendment is simply intended to clarify that Rule 104(a)'s requirement applies to expert opinions under Rule 702." Advisory Committee Notes to 2023 Rule 702 Amendments (citing Rule 104(a)).8

The Advisory Committee's Report to the Standing Committee stated that the "the language of the amendment [conveys that the rule] empowers the court to pass judgment on the conclusion

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⁸ The evidentiary standard on preliminary questions of admissibility (which are for the court, not the jury) under Rule 104(a) is preponderance of the evidence. *See Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987) (holding that preliminary factual findings under Rule 104(a) are subject to the preponderance-of-the-evidence standard). Rule 104(b) deals with a small subset of admissibility questions—questions related to the existence of facts necessary to satisfy conditions to the relevance of particular offered evidence—and prescribes an exception to the general standard (preponderance) for preliminary questions whereby the standard is "sufficient to support a finding" that the fact exists. Fed. R. Evid. 104(b). But the question of whether Rule 702's four requirements to admissibility are satisfied is governed by 104(a) because it does not involve the special circumstances (the conditional-relevance context) addressed by Rule 104(b).

that the expert has drawn from the methodology because the methodology must not only be reliable, it must be reliably applied." Id. (emphasis added). Additionally, the notes stated that "the Committee resolved to respond to the fact that many courts have declared [incorrectly] that the reliability requirements set forth in Rule 702(b) and (d)—that the expert has relied on sufficient facts or data and has applied a reliable methodology—are questions of weight and not admissibility, and more broadly that expert testimony is presumed to be admissible." Id. (It is these court's misapplication of Rule 702 to which Defendant points). Therefore, the changes seem to convey that although a court need not agree with a conclusion to admit it, the Court can exclude a conclusion if it is based on methods that are unreliable (and thus do not serve to reliably substantiate the conclusion.

Defendant argues that none of Plaintiffs' arguments regarding weight and credibility are relevant, because (according to Defendant) all of Plaintiffs' cited cases are of the kind that the revisions sought to abrogate and prevent recurrence of. But Defendant does not identify specific cases or explain how those cases reflect a misapplication of the burden that under Rule 104(a) rests on a proponent of expert testimony offered under Rule 702. In any event—as evident from the discussion below—in order to decide the instant motions, the Court does not need to decide whether any particular cases are of the kind to which the amendment was intended to respond. To the extent that misguided cases of the type that concerned the Advisory Committee are among the cases cited by Plaintiff or decided by the Sixth Circuit, the Court does not have to disagree with

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⁹ This Court is bound to apply both Rule 702 and Sixth Circuit precedent. The comment does not abrogate the Sixth Circuit precedent that this Court is bound to apply. Unless Sixth Circuit precedent demonstrates a contradiction of the burden of proof articulated in the text of Rule 702 as revised, this Court is bound to follow that precedent.

them at this juncture, because the Court has otherwise found that Plaintiffs failed to meet their burden.

B. Motion To Exclude Dr. Greer

1. Dr. Greer's Opinions

Plaintiffs put forward Dr. Greer as an expert who will testify that the Implant broke because of a "critical flaw" that was most likely introduced in the manufacturing process." (Doc. No. 65 at 3). Her opinions rely on a combination of imaging, calculations, and analysis. (*Id.* at 3, 11). Dr. Greer summarizes her underlying opinions as:

- 1) "the material properties and fatigue strength of the implant at the time it was manufactured should have been able to withstand the normal, everyday activities of Mr. Joseph Hill based on the stress imposed by a person of his size," (Doc No. 51-2 at 11);
- 2) "the placement of the device by either the 2014 and 2015 surgeries did not cause the implant to fail in the manner that it did," (*id.*);
- 3) "corrosion was most likely not the cause of failure of the device";
- 4) "nothing done in either the 2014 and 2015 surgeries caused any critical defect to the device to cause its failure," (*id.*);
- 5) "the most likely cause of implant fatigue failure was a critical flaw consisting of two ~150 μm -diameter micropores that are separated by ~200 μm, which were larger than the size of the minimum critical flaw of ~380 μm to initiate fatigue failure in this implant. Such a critical flaw would most likely be introduced during the manufacturing process as there is no reliable evidence I have seen that it was introduced after the original placement," (*id.* at 11–12).

The Court acknowledges that 380 µm is greater than 300 µm, the approximate combined size of two approximately 150 µm micropores. Dr. Greer explained that the 200 µm space between the two micropores factors into the so-called critical flaw being considered "larger" than the "minimum critical flaw" size of 380 µm, stating "a combination of smaller defects that are spaced closely together such that the overall field of defective region meets the critical flaw size, can also serve as [a] fraction initiation site."

(Doc. No. 52-2 at 11).

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 $^{^{10}}$ The symbol " μ m" stands for micrometer (or "micrometre," in British English). A micrometer, also known as a micron, is .001 of a millimeter, i.e., about 0.000039 of an inch. *See micrometre, unit of measurement*, https://www.britannica.com/science/micrometre.

Dr. Greer describes a "critical flaw" as "a [flaw] that's larger than the regular microscopic cracks that are inevitably present in metallurgical and ceramic parts," and "would eventually lead to crack initiation and failure," examples of which include "voids, nicks, notches, and pores." (*Id.* at 7). As described in the fifth point of her summary, she is of the opinion that there was a critical flaw on the Implant that consisted of two very small holes (micropores) located very near one another that—considered collectively and in light of their proximity to one another—weakened the material so as to make it susceptible to fatigue failure. Herein the Court will use "critical flaw" according to Dr. Greer's definition but will use "Critical Flaw" when referring to the bubble-like features Dr. Greer identified on the Implant and claims caused the failure at issue here.

Based on the timing of the Implant's failure (years after the surgeries), the location of the catastrophic crack (i.e., the crack where the Implant ultimately broke), and the imaging of the Implant, Dr. Greer concluded that the failure was a fatigue failure caused by either a critical flaw in the material or overloading. (*Id.* at 4). She then ran a series of calculations to rule out overloading and, from them, concluded that neither the stress of daily activities on the Implant, nor the additional stress that could result if the Implant was placed incorrectly during surgery, would cause the Implant to fail in the manner in which it failed here. (*Id.* at 6–7). "Having ruled out these two possibilities – of incorrect/misaligned placement and/or the material not being able to support the patient's weight and normal activities of daily living under fatigue loading," Dr. Greer concluded, "the only other reasonable possibility of observed material failure would be if the stem had a critical flaw." (*Id.* at 7).

She calculated that to cause this failure, a critical flaw would have to be at least 381 µm, which would be small enough to go undetected during the surgeries if it were inside the Implant. (*Id.* at 10). Dr. Greer's microscopy imaging revealed "bubble-like features," of roughly 100 to 500

μm, located close to one another. (*Id.* at 9). Because two of these "bubble-like features" were each approximately 150 µm in size and only approximately 200 µm apart from one another, Dr. Greer concluded that they (which together comprised the Critical Flaw) were the most likely cause for the fatigue failure. (*Id.* at 10–11). Dr. Greer saw "no reliable evidence . . . that [the Critical Flaw] was introduced after the original placement" and concluded that the Critical Flaw was most likely introduced during manufacturing. In her deposition, she explained that every metal has a "statistical distribution of flaws" that is "inevitable" and "when they coalesce to a larger flaw, that can serve as a stress concentration and a crack-initiation site." (Doc. No. 52-1 at 23:1-7; see also Doc. No. 65-2 at 46:19-24 ("In every metal alloy or a ceramic or a solid material that is susceptible to either ductile or brittle failure, there's a statistical distribution of flaws. And every manufacturing process has a chance of containing one or more [flaws]"); id at 49:4–15 ("the process of fatigue that leads to failure occurs via a coalescence of micropores that are located a certain distance away from one another. Every material that contains flaws has a distribution of flaws . . . [that] may or may not coalesce . . . [and] may or may not propagate into forming a crack."). Dr. Greer noted several additional possibilities that she ruled out, including titanium corrosion and the Critical Flaw having been introduced in surgery. (Doc. No. 51-2 at 11).

2. Dr. Greer's Testimony is Inadmissible

The Court does not agree with all of Defendant's arguments or recitations of the record in litigating this motion. Nevertheless, because (as just described) Dr. Greer's ultimate opinion is based on ruling out causes other than manufacturing—such as load, misalignment, actions during surgery, and corrosion—and because (as discussed below) she is unqualified or otherwise unable to reliably rule out other causes (like misalignment, actions during surgery), her overall testimony is inadmissible.

a. Qualifications

There is no dispute about Dr. Greer's education, experience, and pedigree. Dr. Greer holds an M.S. and Ph.D. in materials science and engineering and, since 2007, has been a professor at the California Institution of Technology (the well-known and well-regarded "Caltech"), where she has taught graduate courses in materials science, mechanical engineering, and medical engineering. Plaintiffs claim that she is qualified to perform the analysis she did here because her calculations and analysis are the same as those that she has taught for fifteen years. In courses she has taught, has taken in her training, or otherwise has observed, hip implants were used as examples for failure analyses. She has extensive experience doing research and overseeing post-docs, labs, and projects that, she purports, apply the same techniques as her opinion here. Among her many professional involvements, she has served on the National Materials Manufacturing Board (NMMB) for the National Academies of Engineering, Science, and Medicine for the last 4 years. She also has a number of patents relating to metals and metallic structures, some of which relate to manufacturing.

It is undisputed¹¹ that Dr. Greer had never performed a failure analysis on a total hip implant prior to her work in this case. She had never attended a total hip replacement surgery and had never read an operative report from a total hip replacement surgery prior to being hired in this case. It is also undisputed that she was unfamiliar with the proper angles of implantation of a hip prosthesis, with how a modular total hip replacement product like the Implant is assembled in the

¹¹ Although there were disputes about certain facts in the arguments for the motions in limine, some of these same facts were then identified as "undisputed for purposes of summary judgment" and are therefore taken as undisputed for ruling on the motion in limine's evidentiary issues related to the Summary Judgment Motion. This is because, in the Court's view, if something is undisputed for purposes of summary judgment, it is undisputed for purposes of a motion in limine that is material to the resolution of that motion for summary judgment. Even so, the Court has serious doubts whether there is any reasonable dispute on any of these undisputed facts.

operating room,¹² and with the instruments used during a total hip replacement surgery. Before forming her opinions, she had not reviewed any transcripts of depositions in this case, including those of Mr. Hill's surgeons, and she did not review Defendant's manufacturing specifications. It is also undisputed that she believes the Implant's design is sound and that she did not review or rely on Dr. Dierckman's report in forming her opinions.¹³

Dr. Greer's opinion that all metals have scattered flaws and that a critical flaw could cause a metal to crack and fail is based on her expertise. And expertise specific to hip implants, which (according to Defendant) Dr. Greer lacks, is not necessarily required to give her opinions about the material of the Implant or her opinion that the material should have been able to withstand a certain load put on it. However, Dr. Greer's conclusions that the failure resulted from the Critical Flaw, and that the Critical Flaw was introduced during the manufacturing process, are based on ruling out all other potential causes of failure. But it is far from clear how Dr. Greer could rule out the other potential causes that she considered. Plaintiffs argue that Dr. Greer ruled out surgery as a cause of the Implant's breakage and was able to do so because general engineering principles can qualify an engineer to render certain opinions on product defects. (Doc. No. 65 at 7). Perhaps, but Plaintiffs nevertheless fail to adequately explain her ability to render opinions that extend beyond engineering principles.

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¹² In her deposition testimony, she guessed that Dr. Perkinson lengthened the femoral stem during the revision surgery by "heat[ing] it up and then pull[ing] on it." (Doc. No. 65-2 255:13–17). But in reality, as mentioned above, length was increased by replacing modular components.

¹³ The (now) undisputed fact that Dr. Greer did not rely on Dr. Dierckman's report in forming her opinions is flatly inconsistent with her statement in her report that "I have reviewed the report of Dr. Brian Dierckman, and also rely on his opinion that the surgeries did not cause any defect in the stem." (Doc. No. 52-2 at 12). Suffice it to say that the Court is disconcerted that this statement was included in Dr. Greer's report.

Her opinion rules out potential alternative causes like the surgeries or other events after the original placement. But these cannot be ruled out without expert knowledge beyond that of engineering principles—in particular, medical expertise that Plaintiffs do not dispute that Dr. Greer lacks. For example, she rules out that the failure was caused by the Implant being placed at the improper angle during surgery, but Plaintiff fails to explain *how* she can give that opinion when (as Plaintiffs do not dispute) she does not know the proper angle at which the Implant should have been placed. If she does not know what angle is improper, then she lacks a basis for saying that an improper angle did not cause the break. Similarly, she lacks a basis to rule out "trauma and blunt force" during surgery, (*see* Doc. No. 65 at 13), because she did not know anything about how the surgery was conducted. Plaintiffs have not established that the operative reports informed Dr. Greer about the forces acting on the Implant during surgery. Nor is it clear that she could have been informed about such forces given that, for example, Dr. Greer did not know how the Implant was lengthened during the surgery (mistakenly attributing such lengthening to a particular component being stretched, when in fact it was replaced).

b. Reliability

Plaintiffs' arguments regarding Dr. Greer's methodology fail for the same reasons. Plaintiffs' primary argument in support of Dr. Greer's methodology is that she teaches in her class the general methodology applied here. But the fact that she has done similar calculations on other objects or on model hip implants in the past does not explain why knowledge of the angle of implantation, forces within the body, and forces during surgery just discussed are unnecessary to reliably perform both the calculations and the analysis needed to rule out other causes of *this* implant's (i.e., the Implant's) failure. Her knowledge (or lack of knowledge) regarding these factors go towards not only her qualifications in terms of the scope (or limitations) of her expertise, but also the reliability of her methods because the Court cannot determine whether her

methodology is reliable without considering her knowledge (or lack thereof) of these factors. Dr. Greer also likewise cannot properly rule out the surgeries as the cause based primarily on the work of other experts, ¹⁴ given that she did not rely on Dr. Dierckman's report. ¹⁵

Furthermore, in considering potential causes other than what happened during surgery, Dr. Greer considered only other causes arising "after the original placement." (See Doc. No. 51-2 at 12 (emphasis added)). She therefore failed to consider anything that occurred between manufacturing and surgery. She cannot properly ground her key opinion—that the manufacturing process was the cause of the failure—on the underlying opinion that there was "no reliable evidence . . . that [the Critical Flaw] was introduced after the original placement" because that

In summary, although Dr. Greer's opinion that the Critical Flaw originated while the Implant was "cross sectioned" well might be within her area of expertise (metallurgy), she has not adequately explained the basis for this view or precluded the possibility that this opinion leads to the circular (and therefore unacceptable) reasoning described above. Accordingly, this opinion is not a valid basis for the opinion that the Critical Flaw did not originate in surgery.

¹⁴ Nor could other experts necessarily rule these out. For example, hypothetical admissible expert testimony that nothing was done incorrectly during surgery does not rule out that events occurring in the normal course of surgery could introduce the Critical Flaw. Dr. Greer as the expert in metallurgy and material sciences would be the expert to testify to how forces (potentially even those identified by other experts) during surgery could affect the metal and create a critical flaw. Plaintiffs have not argued that Dr. Greer considered or was able to consider any such forces.

¹⁵ Dr. Greer did state that the Critical Flaw was unlikely to have originated (been formed) during surgery in part because the micropores (which together comprise the Critical Flaw) "would more likely than not, only be . . . caused when the device was cross sectioned, therefore the micropore defects would probably not have been caused during either surgery when the device was intact." (Doc. No. 52-2 at 12). (The Court takes "when the device was cross sectioned" to mean here "when the device had its interior exposed"). Dr. Greer provides no explanation for why the micropores likely were formed when the Implant was "cross sectioned," and therefore she has not adequately explained why surgery can be excluded as a cause of the formation of the micropores, even accepting that the Implant was not "cross sectioned" during surgery. Moreover she does not preclude the possibility that the "cross sectioning" to which she refers could include cross-sectioning occurring not during manufacturing but rather as a result of the very breaking of the Implant that the micropores are supposed to explain; in that case, Dr. Greer's reliance on "cross sectioning" would be circular, leaving open the possibility that the "cross sectioning" necessary to cause the micropores that caused the break was itself caused by the break, in which case the micropores caused by such "cross sectioning" resulted from break, rather than vice versa as Dr. Greer ultimately concludes. (The undersigned could speculate that any "cross sectioning" occurring after the completion of the manufacturing process would not be the kind of thing that creates micropores, but the Court declines to do so and notes that this is the kind of thing that must be stated and explained for Dr. Greer's methodology to be found reliable).

underlying opinion neglects to consider what happened to the Implant after manufacturing but before the time of the original surgical placement. (*Id.*).¹⁶

Dr. Greer also could not directly link the Critical Flaw to Defendant's manufacturing process.. In her deposition, she suggested that manufacturers should be able to control the size of a flaw in the metal but that it was beyond the scope of her work to determine whether Defendant included the appropriate control measures in its manufacturing process in this instance.¹⁷ She thus draws no connection between (i) the possibility of the Critical Flaw originating in manufacturing as a general matter, and (ii) the Critical Flaw originating in the manufacturing process for the Implant in particular.

Because she cannot reliably rule out other causes, she did not even consider any causes between the time of manufacturing and surgery, and she cannot point to anything in Defendant's manufacture of the Implant that would result in the Critical Flaw (despite acknowledging that the manufacturing process should control for critical flaws), Dr. Greer cannot reliably opine that manufacturing caused the Critical Flaw and, by extension, the Implant's failure. This is true even assuming arguendo that, as she opines, the Critical Flaw caused the Implant's failure.

¹⁶ It is conceivable that Dr. Greer is qualified to give her overarching opinion and could have reliably applied a reliable methodology in reaching that opinion (although this seems unlikely given that her expertise is solely in metallurgy), but Plaintiff has failed to carry its burden to show as much.

¹⁷ In her deposition, Dr. Greer went further to say that her analysis considered Mr. Hill's measurements but that the flaw size for which a manufacturer should control would account for different measurements in consideration of different patients. She testified that she did not do measurements to account for different patients and did not have any idea whether Defendant had done those measurements to determine what its maximum size tolerance for a flaw would be. It is therefore unclear how she could say that the manufacturing process should have eliminated critical flaws of the size that she identified, given that she did not know the minimum flaw size the manufacturing process should have eliminated, and instead knows only what size flaw may have caused the breakage in this instance. This deposition testimony was not relied on by either side in its arguments, but it was included in the exhibits that Plaintiffs submitted. Because it was included in the record, the Court can rely on it, although the Court uses it here only as additional support for reasoning that could otherwise stand alone.

c. Remainder of Dr. Greer's Opinion Testimony is Unhelpful to the Jury

Having excluded certain aspects of Dr. Greer's opinion as inadmissible for lack of qualifications or reliability, the Court now reassess the admissibility of her remaining opinion testimony. Her opinions have been whittled down to the notion that the identified Critical Flaw could have caused (as opposed to did cause) the break and could have originated (as opposed to did originate) in manufacturing—or more specifically, that all metals have a scattered distribution of errors that occur during manufacturing, that a metal's distributed errors could coalesce into the size of the Critical Flaw she identified on the Implant, and a flaw of that size could be sufficient for the Implant to break under fatigue. But as stated above, this remaining opinion does not by itself support the inference that the Implant actually broke due to the Critical Flaw or that anything in Defendant's manufacturing process created the Critical Flaw.

Because Dr. Greer acknowledges other potential causes that neither her testimony nor other evidence in the case serves to eliminate as a cause of the breakage, and because Plaintiff offers nothing besides Dr. Greer's testimony to demonstrate a link between the breakage and Defendant's manufacturing process (as described further below in the discussion of the Summary Judgment Motion), a jury cannot reasonably infer that Defendant's manufacture of the Implant was the cause of the breakage to the exclusion of another potential cause. Accordingly, Dr. Greer testifying about the Critical Flaw would not be helpful to the jury, even if the breakage would not have occurred but for the Critical Flaw. Plaintiffs have not met their burden, and Dr. Greer's testimony is inadmissible.

¹⁸ Dr. Greer's remaining opinions that are omitted here as not helpful to the jury are discussed in part below to demonstrate that they are not even conditionally relevant depending on the success of other arguments. These references demonstrate that even a generous interpretation of Plaintiffs' arguments that addressed these remaining opinions still would not succeed.

It is not lost on the Court that Defendant's expert used an analysis similar to Dr. Greer's and that the two experts disagreed neither on the existence of the Critical Flaw or on the Critical Flaw causing the breakage, but rather on what caused the Critical Flaw. Nevertheless, the admissibility of an expert's opinion is based not on the ultimate *correctness* of those conclusions, but on the *reliability* of those conclusions, and the Court cannot say that Plaintiff has upheld its burden in proving Dr. Greer's opinion was based on a reliable methodology and a reliable application of her methodology to the facts of this case.

d. Case Law Supporting the Exclusion of Dr. Greer's testimony.

Defendant's cited case law supports the Court's conclusion to exclude Dr. Greer's testimony, by emphasizing that an expert's scientific discipline must align with the specifics of his or her testimony. In Jaske v. Zimmer, Inc., No. 03 C 2939, 2010 WL 345897, at *3 (N.D. Ill. Jan. 26, 2010), a court found that a metallurgist's "experience qualifie[d] him to testify with regard to the properties of the metal, where the fracture started, and that the fatigue fracture was 'the result of repetitive forces/stresses applied to the top of the device" but not "that the fracture was the result of the uneven surface of the [knee implant component]." The expert's background in metallurgy meant that he "ha[d] examined the properties of metal components, determined whether those components could withstand certain forces, and looked for defects within the metal itself" and "certainly qualified [him] to testify to the causes of the tibial plate failure had the cause of the failure been a metallurgical defect or was somehow caused by properties of the metal itself." *Id.* However, the expert's testimony went further to offer an opinion that "forces outside of the metal component" caused the failure; the court excluded that opinion because "it [wa]s difficult to see how [he] could testify as to the cause of the fracture where the cause put forth is one that emanated from outside of the metal component" when he was "[w]ithout an expert understanding of the stresses placed on the knee." *Id.*

Jaske distinguished the circumstances there from those in Reed v. Smith & Nephew, 527 F. Supp. 2d 1336 (W.D. Okla. 2007). In Reed, a metallurgist opined that flaws in the metal caused a fatigue fracture after repeated load cycling. F. Supp. 2d at 1344. By not discussing the causes of load cycling, he did not "'delve into the field of biomaterials or biomechanics.'" Jaske, 2010 WL 345897, at *3 (quoting Reed, 527 F. Supp. 2d at 1344). By contrast, Jaske reasoned that although "[i]t is true that a metallurgist is qualified to opine as to the characteristics of metal and the way it behaves under certain circumstances[,]" the metallurgist "lack[ed] any expertise in the biomechanics of the knee, or, the specific circumstances to which the metal was exposed." Id. at *4. The Court summarized the difference: "unlike in [Reed], where the expert was testifying as to internal defects of the metal and whether they contributed to the failure of the implant, [the expert] is attempting to testify that the metal piece fractured as a result of external stress caused by the allegedly defective [implant component.]" Id.

Here, Dr. Greer similarly extends beyond the scope of her expertise in ruling out other causes for the fracture to reach her conclusion. She is qualified to opine on the quality (such as durability and resilience) of the metal and on the extent to which the metal could fracture due to the presence of flaws, and (like the expert in *Reed*) she bases her opinion (in part) on the existence of flaws in the metal itself. But Dr. Greer's opinion about the Critical Flaw is based in part on the biomechanics of the Implant (load and angle) and relies on ruling out other possible external causes like surgery and biomechanics—all of which are matters outside her area of expertise. Therefore, like the expert in *Jaske*, Dr. Greer goes beyond discussing the material (metal) at issue and exceeds her qualification.

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¹⁹ The Court infers "load cycling" to mean the recurring and cyclical stress on a structure, which in the cited cases typically would result from walking or performing similar movement.

C. Motion to Exclude Dr. Merryman

Dr. Merryman opines that there was "an imperfection in the manufacturing process [that] weakened the neck [of the Implant] such that the modest applied moment [from Mr. Hills' walking] caused failure" of the Implant.²⁰ (Doc. No. 54-3 at 7). In reaching that opinion, he relies exclusively on Dr. Greer's report.²¹

In his report, he states that having reviewed Dr. Greer's report, he "understand[s]" that Dr. Greer "identified a microscopic 'critical flaw' that she attributes most likely to having been introduced during the manufacturing process." (Id.). He then states that Dr. Greer's report "describes a 'critical flaw' in the manufacturing process that created a defect in the device." (Id. at 10). Dr. Merryman provides no citation to where in Dr. Greer's report she refers to a critical flaw (or imperfection, a term Dr. Merryman seems to equate with "critical flaw") in the manufacturing process. And in fact she does not do so. Dr. Merryman is inconsistent in how he uses the term "critical flaw" in reference to Dr. Greer's opinion, but Dr. Greer's reference to a "critical flaw" is a reference to something (a micropore or close-together grouping of micropores) in the metallurgical material of which a manufactured item is made, not to something in the process of manufacturing the item. And just as she does not refer to a "critical flaw" in the

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²⁰ It is clear that for current purposes, "applied moment" essentially means "torque."

Aside from Dr. Greer's report, Dr. Merryman has no basis to opine that there is anything wrong with the manufacturing process of the Implant or (for that matter) that there was a manufacturing defect in the Implant. Dr. Merryman agrees that "a microscopic examination would be necessary to be able to conclude that there was a manufacturing defect in the product," absent "other evidence from the manufacturer." (Doc. No. 54-1 162:14–20). He admits that identifying the Critical Flaw in or on the Implant microscopically (as Dr. Greer had) was "something that [he] didn't do because it was outside of [his] area of expertise." (*Id.* 47:21–22). And he agreed that nothing in the manufacturing records led him to believe the manufacturing process caused the Critical Flaw. (*Id.* 164:10–14; Doc. No. 64-1 165:6–166:22). Neither he nor any of Plaintiffs' experts have experience with the Implant's manufacturing process (except to the extent Dr. Greer has experience with the manufacture of metals generally). Without Dr. Greer's purported opinion that a problem in manufacturing process was the basis for the Implant failure, Dr. Merryman is merely speculating that a problem in manufacturing process *could* be the basis for the Implant failure.

manufacturing process, she does not refer to *any* imperfection in the manufacturing process. So Dr. Merryman has relied entirely on an opinion from Dr. Greer's report that simply does not exist. This alone dooms his prospects of showing as required that his opinion is reliable.

But even if Dr. Greer had offered such an opinion, Dr. Merryman could not testify based on that opinion. As explained helpfully by one court in this circuit:

"Experts are permitted wide latitude in their opinions, including those opinions not based on firsthand knowledge. An expert is able to base an opinion on another expert witness for a point of expert knowledge not personally possessed." *In re E.I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 337 F. Supp. 3d 728, 743 (S.D. Ohio 2015) (citations omitted); *see also Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 844 (N.D. Ohio 2011) (reviewing published studies). Thus, experts with appropriate expertise may review scientific literature and other expert reports to form their opinions. *See In re E.I. Du Pont*, 337 F. Supp. 3d at 743–44. But an expert may not simply parrot another expert's opinion. *Hutson*[v. Coviden Holding, *Inc.*, No. 2:13-cv-895], 2015 WL 4040447, at *4 [(S.D. Ohio June 30, 2015)] ("In any event, '[a]n expert must make some findings and not merely regurgitate another expert's opinion.' "(quoting *Buck*, 810 F. Supp. 2d at 844)); *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 741 & n.6 (N.D. Ohio 2014).

In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig., 546 F. Supp. 3d 666, 676 (S.D. Ohio 2021). Dr. Merryman has done nothing more than parrot (regurgitate) Dr. Greer's purported opinion, without any independent findings to support in any way the notion that there was an imperfection in the manufacturing process.

Accordingly, Dr. Merryman's testimony is also inadmissible.

II. Defendant's Motion for Summary Judgment

Given the Court's decisions above, Plaintiffs cannot withstand the Summary Judgment Motion even assuming that the remaining Motions are decided in Plaintiffs' favor. So the Court proceeds directly to a discussion of why it will grant the Summary Judgment Motion, bypassing the other Motions.

A. Legal Standard

Summary judgment is appropriate where there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). In other words, even if genuine, a factual dispute that is irrelevant under applicable law is of no value in defeating a motion for summary judgment. *See id.* at 248. On the other hand, "summary judgment will not lie if the dispute about a material fact is 'genuine[.]" *Id.*

A fact is "material" within the meaning of Rule 56(c) "if its proof or disproof might affect the outcome of the suit under the governing substantive law." *Reeves v. Swift Transp. Co.*, 446 F.3d 637, 640 (6th Cir. 2006) (citing *Anderson*, 477 U.S. at 248), *abrogated on other grounds by Young v. United Parcel Serv.*, 575 U.S. 206 (2015). A genuine dispute of material fact exists if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Harris v. Klare*, 902 F.3d 630, 634-35 (6th Cir. 2018). The party bringing the summary judgment motion has the initial burden of identifying portions of the record that demonstrate the absence of a genuine dispute over material facts. *Pittman v. Experian Info. Sols., Inc.*, 901 F.3d 619, 627-28 (6th Cir. 2018) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Alternatively, the moving party may meet its initial burden by otherwise "show[ing]"—even without citing materials of record—that the nonmovant "cannot produce admissible evidence to support the [existence of a] material fact," Fed. R. Civ. P. 56(c)(1)(B), for example, the existence of an element of a nonmovant plaintiff's claim. If the summary judgment movant meets its initial burden, then in response the non-moving party "must set forth specific facts showing that there is a genuine issue for trial."

Pittman, 901 F.3d at 628 (quoting *Anderson*, 477 U.S. at 250).²² Importantly, "[s]ummary judgment for a defendant [that has met its initial burden as the movant] is appropriate when the plaintiff 'fails to make a showing sufficient to establish the existence of an element essential to [her] case, and on which [she] will bear the burden of proof at trial." *Cleveland v. Pol'y Mgmt. Sys. Corp.*, 526 U.S. 795, 805–06 (1999) (quoting *Celotex*, 477 U.S. at 322).

Any party asserting that a fact cannot be or genuinely is disputed (*i.e.*, any party seeking summary judgment and any party opposing summary judgment, respectively) can support the assertion either by: (a) citing to materials in the record, including, but not limited to, depositions, documents, affidavits, or declarations, Fed. R. Civ. P. 56(c)(1)(A), or (b) "showing" (i) that the adverse party cannot produce admissible evidence to raise a genuine dispute as to that fact or (ii) that contrary to the claim of the adverse party, the materials cited by the adverse party do not actually establish the absence or presence (as the case may be) of a genuine dispute as to that fact. Fed. R. Civ. P. 56(c)(1)(B).

In considering a motion for summary judgment, the court must view the evidence in the light most favorable to the non-moving party. *Tlapanco v. Elges*, 969 F.3d 638, 647 (6th Cir. 2020) (citing *Anderson*, 477 U.S. at 248). Likewise, the "court should view the facts and draw all reasonable inferences in favor of the non-moving party." *Pittman*, 901 F.3d at 628 (citing *Matushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). Credibility judgments and weighing of evidence are improper. *Hostettler v. Coll. of Wooster*, 895 F.3d 844, 852 (6th Cir. 2018). As noted above, where there is a genuine dispute as to any material fact, summary judgment is not appropriate. *Id.* The court determines whether sufficient evidence has

²² Courts (appropriately) at times refer interchangeably to a party being able to raise a genuine issue as to a fact and a reasonable jury being able to find in the party's favor on that fact, and this Court does likewise.

been presented to make the issue of fact a proper jury question. *Id*. The mere existence of a scintilla of evidence in support of the non-moving party's position will be insufficient to survive summary judgment; rather, there must be evidence upon which the jury could reasonably find for the non-moving party. *Rodgers v. Banks*, 344 F.3d 587, 595 (6th Cir. 2003).

A defendant-movant cannot meet its initial burden on motion for summary judgment merely by *claiming* that the plaintiff lacks evidence and essentially challenging the plaintiff to show otherwise. A defendant-movant must—by pointing to materials of record or otherwise—*show* (presumptively, subject to the plaintiff's response) that the plaintiff could not prove his claim by a preponderance. *See* Fed. R. Civ. P. 56(c)(1).²³ In other words, the defendant-movant must produce evidence *tending to show* (though not necessarily *conclusively showing*) that the plaintiff cannot raise a genuine issue as to any material fact.²⁴ *Nickols v. Morris*, 705 F. Supp. 2d 579, 584–85 (N.D. Tex. 2010) ("The party moving for summary judgment has the initial burden of informing the Court of the basis for his motion and producing evidence which tends to show that no genuine

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The undersigned rejects cases that have indicated otherwise. See, e.g., O.M.A., S.r.l. v. Simon DeYoung Corp., No. 1:10CV0861, 2013 WL 7210503, at *3 (N.D. Ohio Mar. 12, 2013) ("[A summary judgment] movant in federal court is not required to . . . provide evidence to show that his opponent has no evidence"), R&R adopted in part, rejected in part on other grounds, No. 1:10 CV 00861, 2014 WL 587171 (N.D. Ohio Feb. 14, 2014); Goldcorp, Inc. v. United States, No. 00-75043, 2002 WL 551042, at *6 (E.D. Mich. Mar. 27, 2002) ("At any rate, even if [the] affidavit were altogether stricken from the record, it appears that the Government still would be entitled to summary judgment in its favor. After all, this affidavit has been provided merely to prove a negative: namely, that there is no evidence that the IRS ever received the protective claim allegedly sent by Plaintiff on or before September 15, 1995. Presumably, then, the Government could have simply asserted this proposition in its brief, and left it to Plaintiff to introduce evidence calling this issue into question.").

²⁴ Notably, a defendant-movant typically can show that there is no genuine issue as to any material fact by showing that there is no genuine issue as to the existence of a fact (usually, the element of a claim) that absolutely needs to exist for the plaintiff to prevail. If the defendant-movant can make this showing, all other facts become immaterial (because the plaintiff necessarily will suffer summary judgment anyway), and thus it can be said that the plaintiff (being unable to show a genuine issue as to *one* material fact) cannot raise a genuine issue as to *any* material fact.

issue as to any material fact exists and that he is entitled to judgment as a matter of law."), *aff'd*, 419 F. App'x 534 (5th Cir. 2011).

B. Plaintiffs' Product Liability Claims

Plaintiffs and Defendant agree that Plaintiffs' strict liability and negligence claims are governed by the TPLA. To succeed on any such claim, a plaintiff must prove a product defect under the TPLA by establishing three elements: (1) the product was defective and/or unreasonably dangerous, (2) the defect or unreasonably dangerous condition existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the product. *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008).²⁵ The Court is persuaded that Defendant succeeds on summary judgment for all the TPLA claims.

The Court begins by outlining the arguments, which will be explained and discussed in detail below. Defendant argues that it is entitled to summary judgment because Plaintiffs' expert testimony is inadmissible (as discussed above), thus leaving Plaintiffs without the expert testimony required to prove a product defect under the Tennessee Products Liability Act ("TPLA"). Defendant contends that the relevant test to determine liability under TPLA is the "reasonably prudent manufacturer" standard and that Plaintiffs cannot establish that Defendant acted without

In diversity cases such as this, we apply state law in accordance with the controlling decisions of the state supreme court. If the state supreme court has not yet addressed the issue presented, we must predict how the court would rule by looking to all the available data. *See id.* "Relevant data include decisions of the state appellate courts, and those decisions should not be disregarded unless we are presented with persuasive data that the [state] Supreme Court would decide otherwise." *Kingsley Assoc. v. Moll PlastiCrafters, Inc.*, 65 F.3d 498, 507 (6th Cir.1995).

Allstate Ins. Co. v. Thrifty Rent-A-Car Sys., Inc., 249 F.3d 450, 454 (6th Cir. 2001) (citation omitted). Herein, when the Court cites a decision of a federal court or Tennessee Court of Appeals, it does so with confidence that the state Supreme Court today would not decide differently with respect to the cited proposition(s).

²⁵ The Sixth Circuit has explained:

reasonable prudence. Defendant also argues that Plaintiffs' experts cannot establish the TPLA's causation element. Defendant argues alternatively that Plaintiff's strict liability claims fail under section (k) of the Second Restatement of Torts. Finally, Defendant maintains that the claims for negligent infliction of emotional distress and loss of consortium fail because the underlying claims fail and, as to the negligent infliction of emotional distress claim, also for lack of proof.

Plaintiffs disagree on all points. They argue that their proffered expert testimony is admissible and sufficient to prove their claims. They contest the use of the "prudent manufacturer" test, arguing instead for the "consumer expectation" test but asserting that they can fulfill the requirements of the TPLA regardless of the test applied. They argue that Defendant has not shown that section (k) is applicable. Finally, they argue that their derivative claims withstand summary judgment because the underlying claims survive and because the derivative claims are supported by sufficient proof.

1. Design- and Warning-Defect Claims

Defendant argues that Plaintiffs conceded their claims based on defects in the Implant's design or warnings by failing to raise such claims in their opposition brief. (Doc. No. 71 at 4). The Court agrees that Plaintiffs conceded all of their claims premised on a theory of design defect or warning defect. Plaintiffs' response in opposition to the Summary Judgment Motion refers to the alleged defect only as a "manufacturing defect." (See e.g., Doc. 66 at 5 (". . . a manufacturing-defect claim (such as this one)"). In fact, the word "design" does not make any appearance in their response, and Plaintiffs' only mention of warnings is in opposition to Defendant's argument based on comment (k) to the restatement. (See Doc. 66 at 13–14). See Nichols v. Mich. City Plant Planning Dept., 755 F.3d 594, 600 (7th Cir. 2014) ("The non-moving party waives any arguments

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²⁶ Because the Court awards summary judgment based on Defendant's other arguments, the Court does not reach this issue.

that were not raised in its response to the moving party's motion for summary judgment."). Moreover, it is undisputed that Plaintiffs' experts do not contest the design of the Implant and believe that the design is sound (Doc. No. 67 at 18–19); this lack of dispute also reflects Plaintiffs' waiver. And, alternatively, Plaintiffs' lack of admissible expert testimony dooms Plaintiffs' ability to show a design defect in any event. The Court will grant summary judgment to Defendant on these claims.

2. Manufacturing-Defect Claim

Under Tennessee law, "[a] manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a). Both Plaintiffs and Defendant discuss "defective condition" and "unreasonably dangerous" (or, to use the noun form, "unreasonable dangerousness") together. Some cases within the Sixth Circuit co-mingle them, and there is some overlap between the two concepts because a defective condition can arise as a result of the product being "unsafe," i.e., dangerous, as made clear below. Nevertheless, the Sixth Circuit has indicated that they are two different things, the existence of either of which is independently sufficient to establish the first element of a manufacturing-defect claim. See Hill v. Kia Motors Am., Inc., No. 20-5690, 2022 WL 557823, at *8-13 (6th Cir. Feb. 24, 2022); Privette v. CSX Transp., Inc., 79 F. App'x 879, 884–90 (6th Cir. 2003) (discussing "defective condition" separately from "unreasonably dangerous"). But see Sigler, 532 F.3d at 484–87 (discussing whether the product was "defective" while using an "unreasonably dangerous" analysis).

a. Defective Condition

The TPLA defines "defective condition" as "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption[.]" Tenn. Code Ann. § 29-28-102(2). "A manufacturer is not required to design a product that is perfect, accident-proof, or incapable of causing injury." *Brown v. Crown Equip. Corp.*, 181 S.W.3d 268, 282 (Tenn. 2005). And an injury itself is not proof of a defect. *Shoemake v. Omniquip Int'l, Inc.*, 152 S.W.3d 567, 573 (Tenn. Ct. App. 2003). For example, "a knife is not defective simply because if the user's hand slips, the blade will cut his or her hand." *Privette*, 79 F. App'x at 886. Instead, "[e]stablishing this element requires only proof, in a general sense and as understood by a layman, that something was wrong with the product." *Browder v. Pettigrew*, 541 S.W.2d 402, 406 (Tenn. 1976).

Having rejected the possibility of Plaintiff succeeding under a design or warning theory of defect, the Court now turns to Defendant's challenge to Plaintiff's manufacturing defect theory. Under a manufacturing defect theory, the alleged unsafe condition of a product relates to how the product was manufactured, not how, for example, it was designed. *Defect*, BLACK'S LAW DICTIONARY (12th ed. 2024) (defining "manufacturing defect" as "[a] departure from a product unit's design specifications; specif., an imperfection in a product that departs from its intended design even though all possible care was exercised in its assembly"). To succeed on a manufacturing defect claim, a plaintiff "must 'trace the injury to some specific error in *construction* . . . of the [product.]" *Fulton v. Pfizer Hosp. Prod. Grp., Inc.*, 872 S.W.2d 908, 912 (Tenn. Ct. App. 1993) (emphasis added) (quoting *Browder*, 541 S.W.2d at 404).

Plaintiffs' experts cannot (and do not) identify anything wrong in the manufacturing process, and Plaintiffs do not have circumstantial evidence to allow a jury to draw in their favor an inference of a defect. After all, Dr. Greer's opinion was that *all* metals have a scattered

distribution of flaws, so the existence of some micropores was a *certainty* regardless of the process; even assuming that in this case, the random scattering resulted in a close juxtaposition of micropores that created a flaw substantial enough to cause the breakage under Mr. Hill's load, such an event does not necessarily mean (or make it inferable) that there was something improper with the *manufacturing process*.

Plaintiffs counter that they have sufficient circumstantial evidence to support an inference that there was a problem in the manufacturing process.²⁷ But given that Plaintiffs are proceeding under a manufacturing-defect theory, Plaintiffs have not explained why the random coalescence of micropores in one place—where two juxtaposed micropores together create a flaw with the potential for breakage—reflects a problem in *manufacturing* as opposed to, e.g., the design choice to use a metal (which according to Dr. Greer will necessarily have micropores, two of which potentially can coalesce). Indeed, there is no dispute among the parties' experts that the design is sound—just as there is no dispute among the experts that the manufacturing process was (as far as

that a party may make her case out by circumstantial evidence under the TPLA is an unremarkable and irrefutable concept . . . "Where a plaintiff is dependent upon circumstantial evidence [to prove a defect in a product], it is sufficient if he makes out the more probable hypothesis, and the evidence need not []rise to that degree of certainty which would exclude every other reasonable conclusion." *Sigler*, 532 F.3d at 486 (Tenn. Ct. App. 1982) (quoting *Motley v. Fluid Power of Memphis, Inc.*, 640 S.W.2d 222, 225).

Hill, 2022 WL 557823, at *9, n.13; see also id. at *8 ("Defect (or causation) might be shown with direct or circumstantial evidence. What matters is that the defect is proven."); Browder, 541 S.W.2d at 404–05 ("[W]e adhere to the body of law which holds that a defect in a product, as well as any other material fact, may be proven by direct evidence, circumstantial evidence, or a combination of direct and circumstantial evidence."). Defendant argues that in seeking to prove a manufacturing defect, Plaintiffs rely impermissibly on the doctrine of res ipsa loquitor when in fact they rely on circumstantial evidence; however, Plaintiffs must still prove that the jury could draw an inference in their favor based on that circumstantial evidence, which as discussed herein, Plaintiffs are unable to do.

²⁷ It is clear that a product liability claim can be established via circumstantial evidence:

they are aware) unproblematic.²⁸ Additionally, Plaintiffs' own expert Dr. Merryman said some implants are idiopathic and just fail inexplicably. (Doc. No. 64-1 112:17–19). ("There are stems or necks that fail every year that are idiopathic, we don't understand exactly why they failed."). Therefore, the Implant's breaking is insufficient to create an inference of a defect because it could have failed for a reason other than Defendant's fault. Plaintiffs' circumstantial evidence is insufficient to show the existence of a genuine issue of material fact as to whether the Implant was in a defective condition.

As in previous cases where a plaintiff could not prove a manufacturing defect, "[i]n this case there is no showing that the plaintiff's injuries are traceable to any specific error in construction . . . of the product." Fulton, 872 S.W.2d at 912. "Plaintiff offered no proof that defendant failed to employ or follow proper manufacturing procedures, or that the design of the product was deficient. No proof was offered that the product should have been made a different way or by using a different material. There is no evidence in the record that defendant deviated from acceptable standards of quality or conduct." Id. Plaintiffs have not demonstrated a genuine issue as to whether the product was manufactured improperly, given that the product allegedly failed in a way (i.e., fatigue fracture of the femoral stem) in which the plaintiff was warned it could fail, that the product was not made with incorrect material (given that its design, including material specifications, has gone unchallenged), and that such material has a known possibility of randomized micropores that could emerge in close proximity so as to create a critical flaw (that under Plaintiff's theory could cause a failure) even if the manufacturer did everything correctly. Id.

²⁸ As discussed above, Dr. Merryman parrots what he believes to be Dr. Greer's opinion that there was an imperfection in the manufacturing process. But actually Dr. Greer gave no such opinion, and so it is accurate to say that Dr. Merryman himself was aware of no problems with the manufacturing process.

The Court pauses for a moment to address the so-called malfunction theory (or malfunction doctrine) since Plaintiffs' arguments appear to be an attempt to assert such a theory. This "resipsa-loquitur-like theory . . . allows plaintiffs in strict liability cases to [have the factfinder] infer defectiveness from the negation of other causes" of an alleged malfunction. Hill, 2022 WL 557823, at *9²⁹ (citing *Balducci v. Hyundai Motor Am., Inc.*, 406 F. App'x 517, 518 (2d Cir. 2011) (deciding under Connecticut law). The theory applies, however, only if the plaintiff can provide at least circumstantial evidence that the product actually malfunctioned, Balducci, 406 F. App'x at 518, which is not necessarily the case even if in retrospect the product did not perform as ideally it would have performed given how events unfolded with the plaintiff. See id. (noting, where the plaintiff alleged injuries from an automobile accident in which her car's airbag did not deploy (as implicitly would have been desirable in retrospect), that the plaintiff "offered no evidence demonstrating an 'absence of other identifiable causes' [whereas] defendant's evidence shows that the air bag's non-deployment was caused by the low speed of [her] car and the type of crash, not a malfunction[.]")). If the plaintiff can show that the product malfunctioned, and if the plaintiff also can negate all other causes for the malfunction other than a product defect, then the malfunction theory is applicable and an inference of a product defect is permissible. See id. at 518– 19 (noting the "crucial additional showing," for application of malfunction theory, of negating "causes for the malfunction other than a product defect" (quoting Fallon v. Matworks, 50 Conn. Supp. 207, 218, 918 A.2d 1067 (Conn. Super. Ct. 2007)).

In *Hill*, which was an appeal of an order granting summary judgment to the product manufacturer, the Sixth Circuit stated, "[r]eference to this theory does not relieve Plaintiffs of

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²⁹ In *Hill*, the Sixth Circuit seemed satisfied that Tennessee law (as perceived today by the Tennessee Supreme Court) would countenance proceeding under the malfunction theory, and the Court here will follow *Hill's* lead.

demonstrating a defect under the TPLA." Hill, 2022 WL 557823, at *10. This proposition is undeniably true; the malfunction theory is properly invoked not to relieve the plaintiff of the requirement to demonstrate a defect, but rather to satisfy (or at least help satisfy) the plaintiff's burden to demonstrate a defect. But Hill may have been suggesting something else. One would think that the malfunction theory, where applicable, is sufficient by itself to raise a genuine issue of material fact as to whether there is a product defect, because it supports a permissible inference of the existence of a product defect. Yet Hill seemingly implied otherwise when it immediately followed the above quote with "Plaintiffs do more than solely argue that the facts of the malfunction alone furnish circumstantial evidence of a defect." Id. The quoted two sentences considered together (and with what follows them) could be construed as saying either that the fact of a malfunction by itself does not establish a defect—which is true because the malfunction theory requires negation of causes of the malfunction other than the defect—or that the applicability of the malfunction theory by itself does not establish a defect sufficient to survive summary judgment. Ultimately, the Court is constrained to reject the second construction, whereby a plaintiff opposing summary judgment would not be credited with raising a genuine issue as to the existence of an element of a claim (here, a product defect), even if he or she raises a permissible inference that the element exists—which simply makes no sense. So the Court proceeds as if a plaintiff can be credited with raising a genuine issue as to the existence of a product defect if he or she can show both of the two prerequisites to the applicability of the malfunction theory.

In *Hill*, the plaintiffs sued the manufacturer after a car suddenly accelerated and would not brake, leading to a multi-fatality accident. The Sixth Circuit determined that a rational trier of fact could conclude that the car was defective based on the plaintiffs' direct or circumstantial evidence, for four reasons. *Id.* at *8. First, a plaintiffs' expert conducted two simulations to test whether the

injury was caused by the design or by the driver, ultimately finding that the accident was more consistent with a design problem.³⁰ Another plaintiffs' expert also "considered relevant human factors" to rule out driver error, so "the remaining primary inference [wa]s that some [design] defect prompted an un-commanded acceleration." *Id.* at *9. Third, as just noted, the plaintiffs' evidence from the post-crash vehicle inspections raised the possibility that driver error did not cause the accident, "thus raising, circumstantially, the possibility of some unspecified . . . malfunction as the source of the acceleration." *Id.* Fourth, statements from the driver, her sister, and eyewitnesses supported that the driver had no control over the vehicle's acceleration despite her attempts to stop the car, supporting the idea "that a sudden acceleration event would not have happened in the absence of a defect." *Id.* In *Hill*, the "[p]laintiffs d[id] more than solely argue that the facts of the malfunction alone furnish circumstantial evidence of a defect. They point to specific circumstantial evidence and testimony to support this conclusion." *Id.* at *10.

In particular, *Hill* involved acceleration and braking systems that should work without fail, meaning that the braking system malfunctioned when the brakes did not work and that the malfunction originated with either the driver or a defect in the acceleration system or braking system. For the four reasons just mentioned, an inference of defect was raised in *Hill*. By contrast—even assuming that a known and warned-of bad outcome (here, fatigue failure of the Implant) constitutes a "malfunction"—in this case other causes cannot be ruled out to make permissible an inference of a defect in the Implant; this is because devices of the same type as the Implant here occasionally fails for unknown reasons, as Dr. Merryman admitted in his deposition. (Doc. No. 64-1 112:17–19. ("There are stems or necks that fail every year that are idiopathic, we

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³⁰ Although *Hill* involved a design defect rather than a manufacturing defect, the Court does not perceive that this difference would render inapt its reliance on *Hill* and consideration of circumstantial evidence in connection with Plaintiff's claim of manufacturing defect.

don't understand exactly why they failed.")). As discussed above, when a device is known to fail for unknown reasons, it is pure speculation that a failure is attributable to a manufacturing defect and not some other unknown cause without evidence supporting one cause over another. Moreover (and as also discussed above), other specific things like surgery could not be successfully ruled out as the cause for the failure of the Implant. Plaintiffs have provided no admissible evidence that a manufacturing defect is *the* cause of the Critical Flaw—or that it is any more likely to cause a breakage than the unknown causes behind the other known failures of devices like the Implant. *See Fulton*, 872 S.W.2d at 911 (finding that a jury could not reasonably infer that an injury resulted from a defendant's negligence, where the only proof of defect was the injury and an expert testified "that on occasion even when the surgeon does everything right and when there is nothing wrong with the devices, the medical implants, the devices can and do fail").

Defendant has met its burden in showing that Plaintiffs cannot succeed in proving a TPLA violation on the basis of a defective condition.

b. Unreasonably Dangerous

There are two tests to determine whether a product is "unreasonable dangerous" pursuant to Tenn. Code Ann. § 29-29-102(8) (2000), namely the consumer-expectation test and the prudent-manufacturer test. To satisfy the consumer-expectation test, a plaintiff must show "that the product was more dangerous than an ordinary consumer 'with the ordinary knowledge common to the community' would have contemplated." *Brown v. Raymond Corp.*, 432 F.3d 640, 643–44 (6th Cir. 2005) (quoting the TPLA). To satisfy the prudent-manufacturer test, the plaintiff shows "that a 'reasonably prudent manufacturer or seller' would not have distributed the product in the condition in which it was sold (the prudent-manufacturer test)." *Id.* (quoting the TPLA). A threshold question is which of the two tests a plaintiff can or must satisfy to show that the product at issue was "unreasonably dangerous." Plaintiffs and Defendant disagree about which test applies, with

Plaintiffs preferring the consumer-expectation test and Defendant preferring the prudentmanufacturer test. However, both assert respectively that they would succeed under either test.

i. <u>Determining Which Test to Apply</u>

"[A]lthough the consumer expectation test is technically applicable to all cases, the test may be inadequate in cases involving complex products that are not familiar to ordinary consumers. In those situations, the prudent manufacturer test is the sole useful test for assessing a ... unreasonably dangerous condition." Coffey v. Dowley Mfg., Inc., 187 F. Supp. 2d 958, 969 (M.D. Tenn. 2002) (citing *Jackson v. Gen. Motors Corp.*, 60 S.W.3d 800, 805 (Tenn. 2001)) (internal citation omitted), aff'd, 89 F. App'x 927 (6th Cir. 2003). The Court pauses momentarily to recognize the paradox presented by the language just quoted. It states the black-letter law that the consumer expectation test always applies, yet it also contemplates that the prudentmanufacturer should and does apply whenever it is better situated to address the facts of the case.³¹ Neither side adequately addressed this paradox in the case law—that the former test always applies even when the latter test also applies. The Court resolves this apparent paradox in this case by reasoning that there are cases in which a plaintiff cannot possibly succeed on the (always applicable) consumer expectation test because (as in this case, as explained below), the plaintiff cannot possibly identify any consumer expectation on which to even base an argument under the consumer expectation test. In these cases, it is appropriate to apply the prudent manufacturer test

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³¹ "The dividing line between the [applicability of the] two tests is not always apparent." *Hill*, 2022 WL 557823, at *10 (collecting cases where the consumer-expectation test applied to "seatbelts, tires, airbags, all-terrain vehicles, the third-row folding seats in sport utility vehicles and station wagons, a hedge trimmer, and even where a restaurant failed to disclose its vegan pizza was topped with pecan chips" and cases where "the complexity of other products preclude[d] the use of the consumer-[expectation] test, thereby prompting the application of the prudent-manufacturer test; these cases have involved industrial forklifts, car radiators, automotive repair tools, medical bronchoscopes, steel rod passenger restraints on an amusement park ride, a heater, and boom-truck cranes.").

because it is "the sole useful test," *Coffey*, 187 F. Supp. 2d at 969, inasmuch as the consumer expectation test is useless because its application is nonsensical where there is no consumer expectation. The Court thus rejects that either test is the "proper" test and instead finds (1) that the consumer-expectation test *always* applies and (2) that for devices of a particular kind and degree of unfamiliarity or complexity, the consumer-expectation test (though technically applicable, as stated in *Coffey*) is necessarily one on which a plaintiff will be unable to prevail due to the lack of consumer expectations,³² effectively forcing the plaintiff to seek to prevail under the prudent manufacturer test.³³ The Court believes that this articulation aligns with a recent articulation of the analysis by the Sixth Circuit. *See Hill*, 2022 WL 557823 at *10–13 (finding that both the consumer-expectation test and prudent-manufacturer test applied); *see also Bradley v. Ameristep, Inc.*, 800 F.3d 205, 211 (6th Cir. 2015). *But see Brown*, 432 F.3d at 644 ("[C]ourts applying the TPLA since *Jackson* have continued to rule that the complexity of a product forecloses the use of the consumer-expectation test.").

ii. Applying the Consumer-Expectation Test

Defendant argues that ordinary consumers do not have an expectation as to the safety of prescription medical devices like the Implant, so the consumer-expectation test is inapplicable and the Court should apply the prudent-manufacturer test. (Doc. No. 56 at 9). Per the Court's discussion above, the consumer-expectation test is always applicable but, as discussed below,

³² In such a situation, one alternatively could say that the consumer-expectation test simply does not apply, but given the black-letter law states that it *always* applies, the better conceptualization here is that it *does* apply—but when applied is revealed to be essentially a nullity.

This is supported by the fact that in many cases, the answer to which test best applies turns on the sufficiency of expert evidence: "While an expert witness is necessary under the prudent manufacturer test, the consumer expectation test, by definition, relies on the expectations of ordinary consumers, not experts." *Coffey*, 187 F. Supp. 2d. at 969. The need to rely on expert evidence suggest that the inquiry requires information beyond the ken of the ordinary consumer.

Defendant persuasively argues that there are no ordinary consumer expectations with respect to the Implant, so Plaintiff cannot succeed in proving that the Implant is unreasonably dangerous under the consumer-expectation test. In considering what products consumers have ordinary expectations of, the Sixth Circuit has stated:

The Tennessee Supreme Court has made clear that "the consumer expectation test does not depend necessarily on a product's complexity in technology or use." *Jackson*, 60 S.W.3d at 806. Instead, the focus is on whether "prolonged use, knowledge, or familiarity of the product's performance by consumers is sufficient to allow consumers to form reasonable expectations of the product's safety." *Id.* "Even a technically complex failure may involve a subject about which an ordinary consumer may have an expectation, as discussed in *Browder*." *Coffey*, 187 F. Supp. 2d at 972.

Hill, 2022 WL 557823, at *11. In a case about a ratchet strap, the Sixth Circuit rejected an attempt by defendants "to confuse the issue by emphasizing the 'complexity" of its product when the product "is a simple device." Bradley, 800 F.3d at 211. The court said, "the obvious failure of a simple component is a suitable candidate for assessment under the consumer expectation test." *Id.* See also Seaton v. Black & Decker (U.S.), Inc., No. 2:20-CV-124, 2021 WL 1395560, at *5 (E.D. Tenn. Apr. 13, 2021) ("[E]ven a technically complex failure may involve a subject about which an ordinary consumer may have an expectation" (quoting Coffey, 187 F. Supp. 2d at 972)) (finding that the consumer-expectation test applied to whether a hedge trimmer was unreasonably dangerous when sold with the battery charged and attached); Hill, 2022 WL 557823, at *11 (ordinary consumer has expectations about the safety and performance of the cruise control and braking system of an automobile); Sigler, 532 F.3d at 486 (accepting a plaintiff's use of the consumer-expectation test for airbags given that airbags are federally required in all new automobiles, the plaintiff alleged a problem only with her particular airbag, and the plaintiff offered a sworn declaration of her expectations that the airbag would work and a brochure by the defendant explaining how the airbags work). Compare Young v. Olympus Am., Inc., No. 07-2547STA, 2012 WL 252645, *6 (W.D. Tenn. Jan. 26, 2012) (reasoning that because an ordinary consumer would not know what makes a bronchoscope's design safe, he or she would not have "minimum safety expectations about a bronchoscope"); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 397 (6th Cir. 2013) (noting in dicta that "the ordinary consumer would not have the medical knowledge necessary to have a reasonable expectation about the safety of [the prescription drug]").

"The Tennessee Supreme Court stated that satisfying the consumer-expectation test 'entails a showing by the plaintiff that ... familiarity of the product's performance by consumers is sufficient to allow consumers to form reasonable expectations of the product's safety." *Sigler*, 532 F.3d at 486 (quoting *Jackson*, 60 S.W.3d at 806). "Under the consumer expectation test, 'a plaintiff is required to produce evidence of the objective conditions of the product as to which the jury is to employ its own sense of whether the product meets ordinary expectations as to its safety under the circumstances presented by the evidence." *Jackson*, 60 S.W.3d at 805 (quoting *Arnold v. Dow Chemical Co.*, 110 Cal.Rptr.2d 722, 737 (2001)).

Hypothetically, a consumer may have expectations that the Implant would not break upon, for instance, his or her first step taken with the Implant. But that is irrelevant here because Plaintiffs do not assert the existence of any expectations of that type, let alone ground their claim on any such expectations. Instead of saying the Implant broke too quickly, Plaintiffs say that it broke "while he was walking in the park with his wife." (*See* Doc. No. 66 at 11). So the Court need not decide here whether there ever could be some reasonable expectations (of one kind or another) for a hip implant; instead, the Court need note only that here there is nothing in the record to support that an ordinary consumer would have reasonable expectations as to the Implant's safety (i.e., its risk of breaking) under the specific conditions Plaintiffs defined. And at least two of Plaintiffs'

three descriptors make no sense. Surely, expectations would not be determined by the location of walking (i.e., in the park as opposed to, say, in his house) or with whom he was walking (i.e., with his wife as opposed to with his friend or his dog).³⁴ At best, Plaintiffs' description limits ordinary expectations to an ordinary activity level, suggesting nothing more than an ordinary consumer would not expect the device to break under normal use. But the fact that the Implant is a prescription device provides evidence that there are no reasonable expectations from ordinary consumers, as the law requires a provider to educate a consumer on what their expectations should be.

Plaintiffs attempt to establish *ordinary consumer* expectations by reference to *Mr. Hill's* expectations. Citing Mr. Hill's declaration, Plaintiffs state that "Mr. Hill was an ordinary consumer in the sense he was a person who was deemed a suitable candidate for a hip implant by his physicians, he was educated on hip implants, and he had a reasonable expectation that the implant would not snap in half inside of his body while he was walking in the park with his wife." (Doc. No. 66 at 11). Plaintiffs do not support the notion that the expectations of a plaintiff alone is cognizable evidence of ordinary consumer expectations. Nor do they argue (as opposed to *conclusorily* assert) that Mr. Hill was an ordinary consumer or that his views are representative of (or a proxy for) the ordinary consumer's views. This Court has identified one example where a

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³⁴ This case is more akin to a forklift's braking system where the ordinary consumer is unfamiliar with that type of industrial machinery, its safety measures, and its risks, even though he or she might be generally familiar with the concept of brakes. *Compare Brown*, 432 F.3d at 644 (applying the prudent-manufacturer test to a forklift with allegedly defective brakes, design, and warnings because it is a complex industrial machine) *with Hill*, 2022 WL 557823, at *11 (applying the consumer-expectation test to cruise control and braking systems in an automobile) ("Based on the ubiquity of cruise control systems and acceleration and braking pedals in vehicles, their mainstay in everyday life, coupled with the fact that brakes and accelerator pedals are some of the most elemental, required components of cars, the average consumer possesses a degree of knowledge of and familiarity with the product's performance which not only exceeds that of industrial forklifts and boom truck cranes . . . but is sufficiently developed to form reasonable expectations about vehicular braking and acceleration safety.").

plaintiff's affidavit alone was accepted as valid evidence of consumer expectations, but the expectations at issue there were of a commonplace consumer product (hedge trimmer). See Seaton, 2021 WL 1395560, at *6 (finding plaintiff's expectations sufficient evidence for a consumer expectation when the plaintiff stated that "he expected the battery would not be attached" to a hedge trimmer when he grabbed the trimmer by the blade). Unlike the plaintiffs in that case, Plaintiffs here have said merely that Mr. Hill expected the device not to break in the way that caused his injuries, not that he had any expectations as to some specific thing that proved to be faulty in a way that ran counter to such expectations.³⁵ The Court realizes that self-serving statements are not categorically excludable in litigation, but it does not accept that a plaintiff's self-serving statement that he did not expect a product to break (when it broke) is sufficient for a reasonable jury to find that the product was actually "unreasonably dangerous" when it broke. Further, Plaintiffs have not explained how a consumer can have reasonable expectations of a product when his or her physician is legally responsible for setting his or her expectations. Rather than a common household item like hedge trimmers, the Implant is a medical device as to which expectations are learned through the informed-consent process and subject to the learnedintermediary doctrine.³⁶ Furthermore, Mr. Hill's expectations are unreasonable when one of the specific warnings that comes with the device is "fatigue fracture of the femoral stem"³⁷ and there

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³⁵ Defendant argues that the consumer at issues is actually Dr. Kurtz, who himself "acknowledged that fatigue fractures can and do happen." (Doc. No. 71 at 6). The Court is not so sure, for multiple reasons, but does not need to reach the issue.

³⁶ An ordinary consumer of a modern car would expect the brakes to work or the airbag to deploy upon forceful impact, regardless of the make and model of the car or who was driving, but it is clear from the testimony that the Implant is not recommended for all patients. Plaintiffs would need to show not only that consumers have expectations about the Implant, but also that consumers' expectations reflect the Implant's function for specific types of patients. Again, the fact that this is a prescription device indicates that the ordinary consumer does not have the medical background in order to form these expectations.

³⁷ The warning also does not specify that it only applies to a certain type of patient or circumstance.

is no contention that Mr. Hill's surgeons provided him inadequate care or failed to relay the warnings.³⁸ (Doc. No. 56 at 17). While a breakage from fatigue fracture of the femoral stem is of course not the desired outcome, its breakage cannot be said to run contrary to reasonable consumer expectations when it is specifically within the scope of the ordinary warnings and informed consent process. In summary, because the breakage (or non-breakage) of the Implant in the manner suffered by Mr. Hill has not been shown to be the subject of reasonable expectations of an ordinary consumer, Plaintiff cannot satisfy the consumer-expectation test.

iii. Applying the Prudent-Manufacturer Test

Defendant asserts the applicability here of the prudent-manufacturer test. And the Court agrees—to Plaintiff's benefit, actually, because its means that Plaintiff has the opportunity to succeed alternatively under a second test, when he could not possibly have succeeded under the first test due to the lack of reasonable expectations from the standpoint of an ordinary consumer.³⁹

In arguing for the consumer-expectation test, Plaintiffs argue that the prudent-manufacturer test categorically does not apply to manufacturing-defect cases, relying on *Sigler v. Am. Honda Motor Co.* (Doc. No. 66 at 5 (citing *Sigler*, 532 F.3d at 484)). *Sigler* did not go so far as to say that the prudent-manufacturer test can never apply to cases based on manufacturing defects. Instead, *Sigler* quoted the district court in that case in saying "[i]t seems to the Court that the prudent manufacturer test applies in design-defect cases, and is much less applicable here, in what appears to be a manufacturing-defect claim." (quoting J.A. at 244–45 (Mem. at 7–8 & n. 1) (citing Robert P. Murrian, *Tennessee's Prudent Manufacturer Test*, 67 TENN. L.REV. 307, 313 (2000)). The Sixth Circuit went on to contrast the manufacturing claim to the design and warning-defect claims involved in previous cases that applied the prudent-manufacturing standard. *Id.* (citing *Brown*, 432 F.3d at 641–42, 649 (involving claims that forklift wheel well and brakes were defectively designed and claim of failure to warn); *Irion v. Sun Lighting, Inc.*, No. M2002-00766-COA-R3-CV, 2004 WL

³⁸ Plaintiffs' Response to the Statement of Undisputed Facts (Doc. No. 67 at 4–5) disputes the admissibility of the "Instructions for Use" that contain the warning (presumably made under their "general objection" to unauthenticated hearsay (*see* Doc. No. 67 at 1)). The "Instructions for Use" is being offered for the fact of what warnings came with the product, not the truthfulness of those warnings, and therefore is not hearsay, and the Court does not see any reason to believe Defendant would not be able to authenticate the document at trial when they included the Instructions for Use in the packaging of each implant as required by federal regulation. Further, Plaintiff has not explained why there is a genuine dispute as to the fact of the warning. Accordingly, the fact is not genuinely disputed.

³⁹ Notably, Plaintiff argues that the prudent-manufacturer test is inapplicable to a manufacturing-defect claim. Nevertheless, they assert success under the latter test in the alternative.

It agrees because, as discussed above, the prudent-manufacturer test is applicable (because it is the more situationally apt test) in addition to the consumer-expectation test whenever the plaintiff has no shot at prevailing under the consumer expectation test due to the lack of reasonable ordinary-consumer expectations.

"Liability under the seller-oriented prudent-manufacturer test attaches when a product would not be put on the market by a reasonably prudent manufacturer or seller because of its dangerous condition." *Hill*, 2022 WL 557823, *12. Under the prudent-manufacturer test, "[t]he manufacturer is presumed omniscient for purposes of this test, meaning that knowledge of a product's [] dangerous condition is imputed [to the manufacturer]." *Hill*, 2022 WL 557823, at *12. The Court then determines whether, based on the imputed knowledge, a reasonably prudent manufacturer would have marketed the item despite its dangerous condition.

When applying the prudent-manufacturer test, courts determine whether a manufacturer acted prudently in marketing the product despite its dangerous condition through a risk-utility test

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^{746823,} at *1 (Tenn. Ct. App. Apr. 7, 2004) (alleging that a "lamp was defectively designed because it did not have a protective guard over the bulb to prevent combustibles from contacting the bulb which generated extreme heat")). Sigler's decision to apply the consumer-expectation test ultimately rested on the fact that the average consumer is familiar with airbags. The plaintiff there successfully showed that "familiarity of the product's performance by consumers is sufficient to allow consumers to form reasonable expectations of the product's safety," by "offer[ing] evidence that an airbag is such a familiar product and that consumers—and, indeed, manufacturers like [defendant]—have expectations about the product's performance and safety." Sigler, 532 F.3d at 486 (quoting Jackson, 60 S.W.3d at 806). Plaintiffs have not persuaded the Court that the prudent-manufacturer test categorically cannot apply to a manufacturing-defect claim.

⁴⁰ The Court does not need to determine whether the relevant "dangerous condition" is (i) a critical flaw in any of Defendant's implants or, instead, (b) the Critical Flaw in the Implant (i.e., Plaintiff's own implant in particular). As discussed below, Plaintiffs' only argument that goes to any factor in the prudent-manufacturer test is the assertion that the manufacturer (Defendant) supposedly could eliminate the dangerous condition by removing dangerous implants (or at least the dangerous implant at issue in this case, i.e., the Implant) from the distribution line. But as also discussed below, nothing in the process that Plaintiffs propose (and chide Defendant for not implementing) would identify a critical flaw in an implant or, more specifically regarding this case, the Critical Flaw in the Implant.

that weighs factors⁴¹ including the "usefulness, costs, seriousness and likelihood of potential harm." *Ray by Holman v. BIC Corp.*, 925 S.W.2d 527, 532 (Tenn. 1996); *Brown*, 181 S.W.3d at 282–83. More specifically, these factors include "the usefulness and desirability of the product, the safety aspects of the product, the availability of a substitute product which would meet the same need, the manufacturer's ability to eliminate the unsafe character, the user's ability to avoid danger, the user's awareness of the danger, and the feasibility of spreading the loss." *Ray by Holman*, 925 S.W.2d at 532 (citing John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 837–38 (1973)); *see also id.* at 533 & n. 10.

Despite not applying the multifactor test directly, Defendant has effectively shown that Plaintiffs cannot establish that the manufacturer could have done anything to eliminate any unsafe character of the Implant or that a user would be unaware of the danger, ⁴² so Defendant has made

"The undersigned has noted on multiple occasions that multi-factor (or balancing) tests, though often having considerable desirability and merit, tend to foster outcomes that are unpredictable on the front end, given such tests' subjectivity." *Memphis A. Phillip Randolph Inst. v. Hargett*, No. 3:20-CV-00374, 2020 WL 5095459, at *16 (M.D. Tenn. Aug. 28, 2020) (quoting Eli J. Richardson, *Eliminating the Limitations of Limitations Law*, 29 Ariz. St. L.J. 1015, 1050 (1997) (proposing a multi-factor test to resolve civil limitations issues, while conceding that when courts "apply[] a multi-factor test, [it is] always an unpredictable endeavor") and Eli J. Richardson, *Taking Issue with Issue Preclusion: Reinventing Collateral Estoppel*, 65 Miss. L.J. 41, 95 (1995) (proposing multi-factor test to resolve collateral estoppel issues, while conceding that its drawback is that it "would produce unpredictable resolutions of collateral estoppel issues, in that it is so flexible and calls for very subjective judicial determinations")). This reality tends not to bode well for the prospects of a multi-factor test to resolve a question as a matter of law at the summary judgment stage.

Acosta v. Peregrino, No. 3:17-CV-01381, 2020 WL 5995049, at *6 (M.D. Tenn. Oct. 9, 2020).

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⁴¹ The undersigned here will reiterate what he has said previously about multi-factor tests generally:

⁴² Defendant points out a relevant contradiction in Plaintiffs' evidence. Mr. Hill states in his declaration that he had expectations about the Implant because of the education his physician provided him, but he previously said in his deposition that he did not recall being told any information by his physician. (Doc. No. 71 at 6) (citing Doc. No. 66-1 at ¶ 4; Doc. No. 71-3 at 63:19–68:5)). Either Mr. Hill did not have information from his physician and therefore could not have based those expectations on the education from his physician (and therefore had provided no consumer expectation to support a claim of unreasonable

an initial showing that Plaintiffs will not succeed on the risk-utility test. Defendant argues that Dr. Greer testified that she had no reason to believe that Defendant's manufacturing process was insufficient to properly produce the Implant, that the flaws in metals can cause cracking through no fault of the manufacturer, that she had no opinion on whether Defendant properly inspected the Implant, and that she thought Defendant would do everything to have a manufacturing process that avoided creating critical flaws in the implants. (Doc. No. 56 at 18–19). Accepting Dr. Greer's statements as fact, these facts all suggest the balancing test would favor Defendant. Indeed, the scenario Dr. Greer's opinion necessarily suggests—that metallic devices, even when manufactured correctly, always carry some risk of its flaws randomly aligning into a critical flaw—seems a good example of the worthiness of the balancing test. There is always a chance—even if only a very low one—of random flaws coalescing into a critical flaw, but that risk of danger is not necessarily so great as to make it unreasonable to market the product. To the extent that it is statistically unlikely for that coalescing to occur, the risk of such coalescing does not make it imprudent to sell the product.

Plaintiffs cannot demonstrate a genuine dispute of material fact that could turn the risk-utility test in their favor. Plaintiffs suggest that Defendant was imprudent in not performing a microscopic inspection of implants in the manufacturing process and that had Defendant done so, it would have identified the flaw (the Critical Flaw) that caused the breakage in Mr. Hill's Implant. (Doc. No. 66 at 12). Plaintiffs further suggest that had Defendant run such a test and thereby learned about that flaw, Defendant would not have then marketed the Implant. (*Id.*). This argument

dangerousness under the consumer-expectation test) or he did receive information from his physician, which would include the product warnings of known risks like fatigue fracture that are unchallenged by Plaintiff. Despite this debate about Mr. Hill's consent to the risk, Plaintiff has conceded that the warnings are sufficient, which the Court takes as a concession of awareness of the risk.

does go (perhaps unintentionally) to one of the above-referenced factors for whether a reasonably prudent manufacturer (treated as having knowledge of the dangerous condition even if it actually did not) would have marketed the product. The factor is the manufacturer's ability to eliminate the unsafe character of the product—with the allegedly potential remedy here being the removal of the Implant (or, as noted in a footnote above, any of Defendant's implants that had a critical flaw) from the supply of Defendant's implants before it had reached the market. But Plaintiffs are unpersuasive in showing that this factor cuts in their favor. Plaintiffs have provided no expert testimony or other evidence to support their assertion that a microscopic evaluation actually would have identified the Critical Flaw during the manufacturing process so as to provide an opportunity to remove the Implant from the market. To the contrary, Dr. Greer supported her manufacturing opinion in part by saying that the Critical Flaw was visible only when the Implant was crosssectioned. Moreover, without establishing that the Critical Flaw actually was created during manufacturing, Plaintiffs cannot suggest that a microscopic examination at the time of manufacture would have provided an opportunity to eliminate the alleged danger of the Implant breaking from the Critical Flaw. Plaintiffs have offered no evidence to support the argument that a microscopic evaluation should have been conducted or that the inspection would have allowed Defendant to eliminate the danger in this case.

Because Defendant has shown that Plaintiffs could not satisfy a reasonable jury by a preponderance that the Implant was defective or unreasonable dangerous, Plaintiffs cannot succeed on their strict liability or negligence claims under the TPLA.

c. Existence of Defective Condition When Leaving Manufacturer's Control

The second element of the manufacturing claim is that the defective or unreasonably dangerous condition existed when the product left the manufacturer's control. As stated above, Plaintiffs

failed to discuss what allegedly went wrong in the manufacturing process, Dr. Greer did not consider the period of time between manufacturing and implantation, and she could not reliably rule out that the Critical Flaw was introduced during or after surgery. Therefore, Plaintiffs have no evidence—direct or circumstantial—that the defect or dangerous condition existed when the Implant left Defendant's control.

C. Loss of Consortium Claim and Negligent Infliction of Emotional Distress Claim

Plaintiffs do not dispute Defendant's assertion that their loss of consortium claim is a derivative claim that rests on the underlying manufacturing-defect claim. (*See* Doc. No. 66 at 14); *Hunley v. Silver Furniture Mfg. Co.*, 38 S.W.3d 555, 557 (Tenn. 2001). Likewise, Plaintiffs do not dispute that their negligent infliction of emotional distress claim rests on a finding that Defendant acted negligently in the manufacture of the Implant. (*See* Doc. No. 66 at 15). Because the underlying manufacturing-defect claims fail for the reasons described above, these claims also fail.

The Motion on Tracy Hill's Declaration argued that the declaration was improper support for the NIED claim. Because the NIED claim fails, Tracy Hill's Declaration is irrelevant to any pending claims. Accordingly, the Motion on Tracy Hill's Declaration is DENIED as moot.

CONCLUSION

For the foregoing reasons, given herein Plaintiffs' MIL (Doc. No. 40) will be DENIED as moot, the Motion to Exclude Dr. Greer (Doc. No. 51) will be GRANTED, the Motion to Exclude Dr. Merryman (Doc. No. 53) will be GRANTED, the Summary Judgment Motion (Doc. No. 55) will be GRANTED, the Motion on Expert Declarations (Doc. No. 73) will be DENIED as moot; and the Motion on Tracy Hill's Declaration (Doc. No. 74) will be DENIED as moot.

A corresponding order will be entered separately.

ELI RICHARDSON

UNITED STATES DISTRICT JUDGE